1625

CERTIFICATION OF FACSIMILE TRANSMISSION

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MARTIN A. HAY
Type or print name of person signing certification

Signature

May 9, 2003
Date

6/12/03

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	LIEBESCHUETZ, John Walter LYONS, Amanda MURRAY, Christopher William RIMMER, Andrew David YOUNG, Stephen Clinton CAMP, Nicholas Paul JONES, Stuart Donald MORGAN, Phillip John RICHARDS, Simon James WYLIE William Alexander MASTERS, John Joseph WILEY, Michael Robert	
Serial No.	:	09/926,712	)
Filed	:	06 December 2001	) Group Art Unit:
For	:	Serine Protease Inhibitors	) 1625
Docket No.	:	00111/US1	)
Examiner:		Aulakh, Charanjit	

By Facsimile (without Copies of References)

Confirmation (with Copies of References) by Courier

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
US Patent & Trademark Office
2011 South Clark Place
Customer Window, Mail Stop Patent Response
Crystal Plaza Two, Lobby, Room 1B03
UNITED STATES

Sir:

Telephone Communications with the Examiner

The undersigned left a voice mail message for the Examiner on March 11, 2003 indicating that he was preparing an Information Disclosure Statement and also intended to submit additional claims directed to methods of use of the claimed compounds. These methods of use are presently claimed in co-pending application Serial No. 09/926,716, which is intended to be abandoned. On May 6, 2003 the undersigned telephoned the Examiner to apologize for the delay in submitting the Information Disclosure Statement, and informed the Examiner that the Applicants will not be seeking to introduce method of use claims at this time. Applicants reserve the right to pursue claims to methods of use at a later date.

Background Information

This application is part of an international portfolio of patent applications protecting serine protease inhibitors, all of which are in the care of the undersigned. Some of these applications now belong to Tularik Limited, a subsidiary of Tularik Inc in South San Francisco, and some of them now belong to Eli Lilly and Company in Indianapolis. The history of all of these applications traces back to a research project on serine protease inhibitors started by a small company in the undersigned's home town, Macclesfield, U.K., known as Proteus (later Protherics) Molecular Design Limited. The original applications encompassed benzamidine and aminoisoquinoline compounds, and now belong to Tularik Limited. As the research effort has continued and involved researchers at other sites, two different directions have been followed. One direction has led to compounds that are selective for the serine protease, tryptase. These compounds generally possess an aminomethylphenyl group (corresponding

with R_2 in formula (I)), and are protected by Tularik applications. The other direction has led to further compounds that are selective for the serine protease, Factor Xa. These compounds are protected by Lilly applications. The claims in the Lilly applications have generally been drafted so that aminomethylphenyl compounds are not covered. Thus, all but one contain a proviso excluding aminoalkyl-substituted compounds (The Examiner is referred to the definition of R_1 in Claims 1 and 29 of the present application). The one exception, Serial No. 09/926,716, which contains generic method claims reading on both aminomethylphenyl and non-aminomethylphenyl compounds, is intended to be abandoned.

In order to assist the Examiner to have a complete picture of the portfolio, a listing of all co-pending U.S. applications and patents in the portfolio is attached. When the Examiner inspects these co-pending applications, the Examiner will note that in the more recent applications, including the present application, the claimed inventions are further distinguished one from another by the definitions of the group L-Lp(D)$_n$.

Thus, the first applications filed in the portfolio were WO 99/11657 and WO 99/11658, directed to aminoisoquinoline and benzamidine compounds. Serial number 09/988,082, is a continuation-in-part of WO 99/11658, and also of WO 00/77027, as described below.

Next came three PCT applications, all filed on the same day and claiming priority back to common priority documents: WO 00/76971 (of which the present application is the national stage), WO 00/77027 and WO 00/76970. WO 00/77027 claimed aminomethylphenyl compounds. It has not entered the national stage, but as described above, serial number 09/988,082 is a continuation-in-part of this application. WO 00/76971 claimed compounds which do not have an aminomethylphenyl group (see the proviso in the definition of

R_1) nor an aminoisoquinoline group (see the proviso in the definition of R_2). WO 00/76970 contained method of use claims reading on the compounds of WO 00/77027 and WO 00/76971. It has entered the national stage as serial number 09/926,716 and has been allowed, but is intended to be abandoned.

Next came four more PCT applications: WO 01/96303, WO 01/96304, WO 01/96323 and WO 01/96296, all claiming priority back to WO 00/76971. The Examiner will note from the file for the present application, that the claims have been amended in the application so as to exclude the compounds now claimed in these four co-pending applications.

Two further PCT applications were also filed and have entered the national stage: WO 01/44226 and WO 01/96305. These claim aminomethylphenyl compounds, and claim priority back to WO 00/77027.

Thus, having regard to the definitions of R_2 and Lp in Claim 1 of the present application, and in particular to the proviso excluding compounds in which R_2 is aminoisoquinolyl and the proviso excluding compounds in which R_1 is aminoalkyl, it is believed that the claims in the present application are distinguished from the claims in the other Tularik and Lilly patents and applications.

Effective from December 15, 1999, the rights in the present application, including the rights arising in the priority applications, were subject to an obligation to assign to Lilly, according to a contract executed by Protherics Molecular Design Limited and Eli Lilly and Company on that date.

Information Disclosure Statement

As a means of complying with the duty of disclosure, Applicant's submit an "Information Disclosure Statement by Applicant" on PTO Form PTO/SB/08A for consideration by the Examiner. Since this statement is being submitted during the

period specified in 37 C.F.R. § 1.97(b), it is believed that no fee is due for this submission. However, should an Office Action on the merits have been mailed, please charge Deposit Account No. 50-1230 in the amount of the fee under 37 C.F.R. § 1.17(p), and consider the information under 37 C.F.R. § 1.97(c).

It is understood that the Examiner has received a copy of the International Search Report and copies of the documents cited therein (documents A1 and B1-B7). If this is incorrect, the Examiner is kindly requested to contact the undersigned to request copies.

Applicants would like to draw the Examiner's attention to the following points relating to certain of the cited documents:

WO 99/11657 (B1), WO 99/11658 (B2) and WO 98/47876 (B3) variously disclose compounds corresponding to formula (I) in which R_2 or Lp comprises a benzamidine, aminoisoquinoline or dihydroaminoisoquinoline group. WO 99/11658 (B2) also specifically discloses, as intermediates to benzamidines, certain compounds corresponding to formula (I) in which R_2 is phenyl substituted by cyano. See Examples 88, 150, 152, 153 and 186, which correspond with compounds of formula (I) in which Lp is 4-aminomethylcyclohexyl (88, 152) or 4-methylphenyl (150, 153, 186). Applicants have **not** yet amended Claim 1 to distinguish it from these examples, because there may be co-pending applications by Cor Therapeutics, Inc also disclosing and claiming nitrile compounds (see under "International Applications That May Have U.S. Counterparts" below).

US 5,346,907 (A1) discloses, in Examples 61 and 62, compounds corresponding to formula (I) in which Lp is 2-propylpiperidinyl. Present Claims 1 and 29 do not read on these specific compounds. WO 91/00725 (B8) is of the same

family as US 5,346,907 (A1), but includes a broader disclosure.

WO 99/25686 (B9) discloses, as compound 2099, a compound corresponding to formula (I) in which Lp is 1-(4-chlorobenzyl)piperidin-4-yl. Present Claims 1 and 29 do not read on this compound.

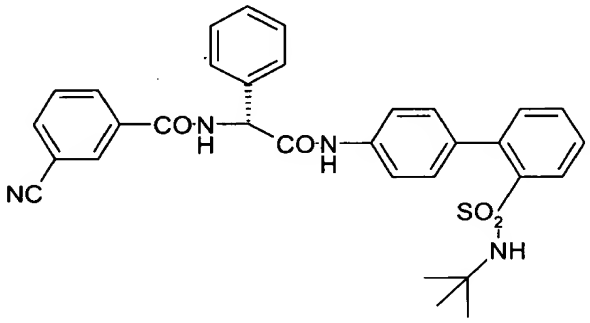
Documents B15 to B18 were published after the international filing date of the present application. They are not believed to be available as references under 35 U.S.C. 102(e).

EP 623,596 (B23), EP 648,780 (B24), EP 686,642 (B25), US 5,583,146 (A4), EP 796,866 (B26) and WO 97/49404 (B27) disclose N-acyl pyrrolidines and N-acyl piperidines as thrombin inhibitors, and intermediates useful in their preparation. The definitions of the N-acyl group may overlap, generically, with the definition of R_2-X-X-Y(Cy)- in Claim 1 of the present application. The Examiner's attention is drawn in particular to EP 623,596 (B23): page 15, intermediate amine resulting from reduction of azide XIX, page 21, intermediate aldehyde XXXII, page 22, intermediate alcohol XXXIV, page 23, intermediate aldehyde XXXV, page 24, intermediate amine 24; EP 648,780 (B24): page 7, intermediate II; EP 686,642 (B25): page 14, intermediate ester IV and acid V; US 5,583,146 (A4): Column 45, intermediate amine from reduction of azide XIXa, Column 50, intermediate aldehyde XXXIIa, column 52, intermediate XXXVIIa, Column 59, line 50 intermediate acid; EP 796,866 (B26): page 9, intermediate acid II; and WO 97/49404 (B27): page 13, intermediate acid II.

Documents B28 to B31 were all published after the filing date after the international filing date of the present application. They are not believed to be available as references under 35 U.S.C. 102(e). However, they may contain U.S. counterparts.

The Cor Therapeutics, Inc applications (B29 to B31) were filed on 24 May, 2000 and claim priority from one of four U.S. provisional applications filed on 24 May, 1999.

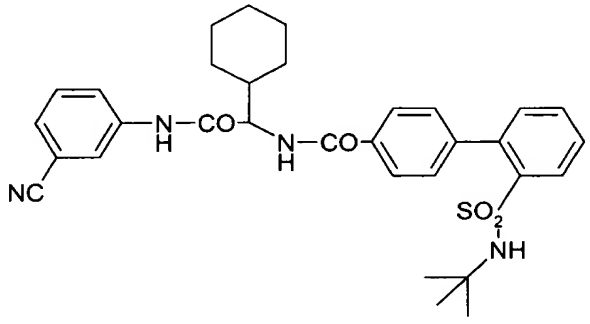
WO 00/71493 exemplifies, as an intermediate:



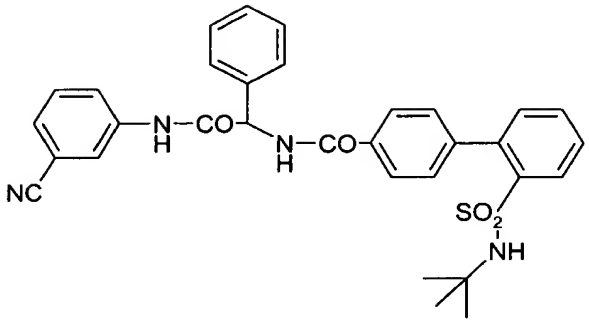
Example 25

which falls within the scope of Claim 1. This compound is also exemplified in the priority document (60/135,820) and as Example 16 in WO 00/71507. The Examiner will appreciate that this compound corresponds to formula (I) in which R_2 is phenyl substituted at the 3-position by a cyano group, and Lp is a biphenyl group substituted on the phenyl portion by a group R_3 which is ortho-t-butylaminosulphonyl (an alkylaminosulfonyl group).

WO 00/71508 exemplifies, as intermediates:



Example 34



Example 35

The Examiner is referred to Example 33, to which Examples 34 and 35 refer. The Examiner will appreciate that these compounds corresponds to formula (I) in which R_2 is phenyl substituted at the 3-position by a cyano group, and Lp is a biphenyl group substituted on the phenyl portion by a group R_3 which is ortho-t-butylaminosulphonyl (an alkylaminosulfonyl group).

Conclusions

Product Claims 29 to 41 are believed to be allowable.

Claim 1 reads on nitrile compounds exemplified as intermediates in WO 99/11578, which is a prior publication. It also reads on nitrile compounds exemplified as intermediates in WO 00/71493, WO 00/71507 and WO 00/71508, which are not prior publications but which may have U.S. counterpart applications.

Respectfully submitted,

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Agent for Applicants
Registration No. 39,459
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UNITED KINGDOM

May 9, 2002

Co-Pending Lilly and Tularik Applications and Patents

Co-pending Applications Assigned to Eli Lilly and Company

09/926,716 (national stage of WO 00/76970), filed 06 Dec 2001
10/030,186 (national stage of WO 01/96304), filed 04 Feb 2002
10/030,187 (national stage of WO 01/96323), filed 04 Feb 2002
10/030,188 (national stage of WO 01/96303), filed 04 Feb 2002
10/030,189 (national stage of WO 01/96296), filed 04 Feb 2002

Remarks:

It is presently intended that co-pending application serial number 09/926,716 will be abandoned, but Applicants reserve the right to introduce method of use claims into the present application.

Co-pending applications serial nos. 10/030,186 to 10/030,189 claim priority under 35 U.S.C. § 119 from PCT/GB00/02302 (WO 00/76971), of which the present application is the national stage.

On national stage entry, Applicant presented an amended set of compound claims that was drafted to avoid double patenting with the compound claims of these co-pending applications.

Co-pending Applications and Patents Assigned to Tularik Limited

US 6262069 and **US 6420438** (national stage of WO 99/11657 and continuation thereof)
09/988,082, filed 19 November, 2001 as a continuation-in-part of WO 00/77027) and of Serial No. 09/485,678 (allowed then abandoned), which was the national stage of WO 99/11658).

10/148,174 (national stage of WO 01/44226), filed Dec 13, 2002
10/296,245 (national stage of WO 01/96305), filed Jun 12, 2001

Remarks:

09/988,082 claims compounds corresponding to formula (I) in present Claims 1 and 29 in which R_2 is phenyl bearing an unsubstituted or substituted amidino or aminomethyl group.

The definition of possible substituents on a phenyl R_2 group does not include these groups. The Examiner's attention is drawn in particular to the definition of R_1 and to the limitation that the group R_1 cannot be an unsubstituted aminoalkyl group. For completeness, it is pointed out that the claims in co-pending Lilly application 09/926,716, which is to be abandoned, do not include this limitation.

Co-pending applications serial numbers 10/148,174 and 10/296,245 claim compounds that are selective for the serine protease tryptase. The compounds correspond to formula (I) in the present application in which R_2 is phenyl substituted by aminomethylphenyl. Such compounds fall outside the scope of Claims 1 and 29 by virtue of the limitation that R_1 cannot be unsubstituted aminoalkyl. The compounds of the present application are selective for the serine protease Factor Xa.

PTO/SB/08A (04-03)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 6

Complete if Known	
Application Number	09/926,712
Filing Date	12/06/2001
First Named Inventor	Liebeschuetz, J. W.
Art Unit	1625
Examiner Name	Aulakh, Charanjit
Attorney Docket Number	00111/US1

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	US- 5346907	09-13-1994	Kerwin et al	Examples 61-62
	A2	US- 5518735	05-21-1996	Sturzebecher et al	
	A3	US- 6140351	10-31-2000	Arnaiz et al	
	A4	US- 5583146	12-10-1996	Kimball et al	
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	B1	WO 99/11657	03-11-1999	Proteus		
	B2	WO 99/11658	03-11-1999	Proteus		
	B3	WO 98/47876	10-29-1998	Akzo		
	B4	EP 617032 A1	09-28-1994	J. Uriach & Cia		
	B5	WO 97/19927	06-05-1997	Smithkline Beecham		
	B6	EP 564924 A2	10-13-1993	Miles Inc		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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(Use as many sheets as necessary)

Sheet 2 of 6

Complete if Known	
Application Number	09/926,712
Filing Date	12/06/2001
First Named Inventor	Liebeschuetz, J. W.
Art Unit	1625
Examiner Name	Aulakh, Charanjit
Attorney Docket Number	00111/US1

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	B7	EP 441226 A2	08-14-1991	J Uriach & Cia		
	B8	WO 91/00725	01-24-1991	Abbott Labs		
	B9	WO 99/25686	05-27-1999	Teijin Ltd	Compound 2099	
	B10	WO97/24118	07-10-1997	Rhone Poulenc		
	B11	WO99/00121	01-07-1999	Eli Lilly and Co		
	B12	WO99/00126	01-07-1999	Eli Lilly and Co		

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Sheet 3 of 6

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	B13	WO99/00127	01-07-1999	Eli Lilly and Co		
	B14	WO99/00128	01-07-1999	Eli Lilly and Co		
	B15	WO00/39092	07-06-2000	Eli Lilly and C		
	B16	WO 00/39111	07-06-2000	Eli Lilly and Co		
	B17	WO 00/39117	07-06-2000	Eli Lilly and Co		
	B18	WO 00/39118	07-06-2000	Eli Lilly and Co		

Examiner Signature		Date Considered	

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Sheet 4 of 6

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Art Unit	1625
Examiner Name	Aulakh, Charanjit
Attorney Docket Number	00111/US1

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	B19	WO 99/32477	07-01-99	Schering		
	B20	WO 98/57951	12-23-98	Du Pont		
	B21	WO 97/23212	07-03-97	Du Pont		
	B22	WO 96/12499	05-02-96	Du Pont		
	B23	EP623596A1	11-09-94	Bristol-Myers		
	B24	EP648780A1	04-19-95	Bristol-Myers		

Examiner Signature		Date Considered	

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Sheet 5 of 6

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Examiner Name	Aulakh, Charanjit
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	B25	EP686642A2	12-13-95	Bristol-Myers		
	B26	EP796866A1	09-24-97	Eli Lilly and Co		
	B27	WO 97/49404	12-31-97	Eli Lilly and Co		
	B28	WO 01/05784	01-25-01	Du Pont		
	B29	WO 00/71493	11-30-00	Cor Therapeutics		
	B30	WO 00/71507	11-30-00	Cor Therapeutics		

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 6 of 6

Complete if Known	
Application Number	09/926,712
Filing Date	12/06/2001
First Named Inventor	Liebeschuetz, J. W.
Art Unit	1625
Examiner Name	Aulakh, Charanjit
Attorney Docket Number	00111/US1

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	B31	WO 00/71508	11-30-00	Cor Therapeutics		

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